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November 24, 2003

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37 C.F.R. 1.8

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November 24, 2003
Date

Robert E. Hanson

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Re: *SN 10/077,591 "PLANTS AND SEEDS OF CORN VARIETY I450436" – James Larkins; Our Ref. DEKA:299US; Client Ref. [34-63(52341)]*

Commissioner:

Enclosed for filing in the above-referenced patent application is:

1. An Appeal Brief (an original and two copies);

2. A check in the amount of $330.00 in payment of the required filing fee; and

3. A return postcard to acknowledge receipt of these materials. Please date stamp and mail this postcard.

If the check is inadvertently omitted or should any additional fees be required under 37 C.F.R. §§ 1.16 to 1.21 for any reason relating to the enclosed materials, or should an overpayment be included herein, the Commissioner is authorized to deduct or credit said fees from or to Fulbright & Jaworski L.L.P. Account No.: 50-1212/DEKA:299US.

Respectfully submitted,

Robert E. Hanson
Reg. No. 42,628

REH/vv
Enclosure

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
James Larkins

Serial No.: 10/077,591

Filed: February 15, 2002

For: PLANTS AND SEEDS OF CORN VARIETY I450436

Group Art Unit: 1632

Examiner: Fox, D.

Atty. Dkt. No.: DEKA:299US

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November 24, 2003
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Robert E. Hanson

BRIEF ON APPEAL

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: James Larkins	Group Art Unit: 1632
Serial No.: 10/077,591	Examiner: Fox, D.
Filed: February 15, 2002	Atty. Dkt. No.: DEKA:299US
For: PLANTS AND SEEDS OF CORN VARIETY I450436	

BRIEF ON APPEAL

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellants hereby submit an original and two copies of this Appeal Brief. The fee for filing this Appeal Brief is attached hereto. The date for filing the instant Brief is November 24, 2003, based on the receipt of the Notice of Appeal by the Patent and Trademark Office on September 22, 2003. No additional fees are believed due in connection with the instant paper. However, should any fees be due, the Commissioner is authorized to withdraw the appropriate fee from Fulbright & Jaworski L.L.P. Deposit Account No. 50-1212/DEKA:299US. Please date stamp and return the enclosed postcard to evidence receipt of this document.

I. REAL PARTIES IN INTEREST

The real party in interest is Monsanto Company, the parent of wholly-owned subsidiary DeKalb Genetics Corporation, the assignee of this application.

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II. RELATED APPEALS AND INTERFERENCES

Appeals were filed in U.S. Patent Application Ser. No. 09/772,520; U.S. Patent Application Ser. No. 09/788,334; U.S. Patent Application Ser. No. 09/606,808; and U.S. Patent Application Ser. No. 10/077,589, which are also directed to inbred corn plants and therefore may have a bearing on the Board's decision in the pending appeal.

III. STATUS OF THE CLAIMS

Claims 1-31 were filed with the application and were pending at the time of the final Office Action. Claims 1-15 and 17-23 were allowed in the final Office Action and claims 16 and 24-31 were rejected. No amendments have been made subsequent to the final Office Action. Claims 1-31 are currently pending. The rejection of claims 16 and 24-31 is the subject of the instant Appeal. A copy of the appealed claims is attached hereto as Appendix 1. A copy of the pending claims is attached as Appendix 2.

IV. STATUS OF AMENDMENTS

No amendments have been made subsequent to the final Office Action.

V. SUMMARY OF THE INVENTION

The invention relates to the novel inbred corn plant designated I450436 and seeds or populations of seed thereof. Specification at page 5, lines 3-19. The invention also relates to male sterile and single locus converted plants of I450436. Specification at page 6, lines 6-27. The invention further relates to methods for breeding I450436 with other corn plants, and hybrid plants produced thereby. Specification from page 7, line 15 to page 9, line 12.

VI. ISSUES ON APPEAL

(1) Were claims 16 and 27-30 properly rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out the subject matter which applicants regard as the invention?

(2) Were claims 16 and 24-31 properly rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to convey that the applicants were in possession of the claimed invention?

(3) Were claims 16 and 24-31 properly rejected under 35 U.S.C. §112, first paragraph, as not being enabled?

(4) Is claim 31 properly rejected under 35 U.S.C. §102 as being anticipated?

VII. GROUPING OF THE CLAIMS

Claim 16 is directed to a corn plant capable of expressing all the physiological and morphological characteristics of the corn variety I450436 that further comprises a nuclear or cytoplasmic gene conferring male sterility. None of the other claims are directed to this subject matter and thus distinct issues are raised under 35 U.S.C. §112, first paragraph. The claim therefore stands or falls alone. Claims 24-26 are directed to hybrid plants produced by crossing the inbred corn plant of the invention. None of the other claims are directed to this subject matter and thus distinct issues are raised by the claims under 35 U.S.C. §112, first paragraph. Claims 24-26 therefore stand or fall together but separately from the remaining claims. Claims 27-30 are directed to a corn plant of variety I450436 that comprises a single locus conversion. None of the other claims are directed to this subject matter and thus distinct issues are raised by the claims under 35 U.S.C. §112, first paragraph. Claims 27-30 therefore stand or fall together but separately from the remaining claims. Claim 31 is directed to a method of producing an

inbred corn plant derived from the corn variety I450436. Distinct issues are raised by the claim under 35 U.S.C. §112, first paragraph. Claim 31 therefore stands or falls separately from the remaining claims.

VIII. SUMMARY OF THE ARGUMENT

The indefiniteness rejections fail because the metes and bounds of each of the rejected claims are clear to one of skill in the art in view of the well known meaning of the terms used and the language of the claims.

The written description rejections fail because the claimed subject matter has been fully described. Each of the claimed hybrid plants and seeds having inbred corn plant I450436 as one parent have as half of their genome the same genetic contribution from I450436, given that corn plant I450436 is inbred. This structural characteristic is readily detectable and thus defines the claimed plants. The claimed plants are produced using any second plant, thus written description with regard to the second parent is satisfied based on the countless corn varieties known to those of skill in the art, including the more than 300 corn varieties for which utility patents have previously been issued. Methods of crossing the claimed corn variety have been fully described in the recited steps, and such corn breeding steps were well known in the art. Single locus conversions of I450436 were also fully described, in that well more than a representative collection of single locus conversion traits are described in the specification and were well known to those of skill in the art. The single locus conversion traits themselves are further not being claimed, rather it is corn plant I450436 comprising a single locus conversion that is claimed. The written description requirement has thus been fully satisfied.

The enablement rejections fail because Appellants working examples and descriptions in the specification fully enable the claimed subject matter. The Examiner has improperly

disregarded this evidence and failed to support the rejections in contradiction to the standards of the APA.

The anticipation rejection of claim 31 fails because step (a) of the claimed method requires the use of corn variety I450436. The Examiner has acknowledged the novelty and nonobviousness of corn variety I450436 based on the lack of rejection of claims 1-15. The prior art therefore fails to teach or suggest all elements of the claim.

IX. ARGUMENT

The Examiner has finally rejected claims 16 and 27-30 as being indefinite under 35 U.S.C. §112, second paragraph; claims 16 and 24-31 as lacking an adequate written description in the specification under 35 U.S.C. §112, first paragraph; and claims 16 and 24-31 as lacking enablement under 35 U.S.C. §112, first paragraph. Appellants respectfully request that the Board reverse the rejections for the reasons set forth below.

A. The Claims Are Definite Under 35 U.S.C. §112, Second Paragraph

The Examiner rejects claims 16 and 27-30 as broadening the scope of the claims from which they depend. Claim 16 depends from claim 15 and therefore incorporates all of the limitations of claim 15, but further specifies the added characteristic of male sterility. In particular, the claim is directed to the corn plant of claim 15 "further comprising a nuclear or cytoplasmic gene conferring male sterility." Therefore an additional limitation not required by claim 15 is specified. Similarly, claim 27 is directed to the corn plant of claim 5 "further defined as having a genome comprising a single locus conversion." Again, the claim specifies an additional characteristic relative to the main claim while including all of the limitations. Therefore, both claims (1) contain a reference to the parent claim from which they depend, (2) contain a further limitation of the main claim, and (3) incorporate all elements of the claim from

which they depend. The claims are therefore in proper dependent form pursuant to 37 C.F.R. §1.75(c) and are fully definite. Reversal of the rejection is therefore respectfully requested.

B. The Written Description Rejection of Claims 16 and 24-31 Under 35 U.S.C. §112, First Paragraph Is Improper

1. Male Sterile and Single Locus Converted Plants Are Described

The Examiner rejects claim 16, which is directed to the corn plant of claim 15 further comprising a nuclear or cytoplasmic gene conferring male sterility, as lacking written description under 35 U.S.C. §112, first paragraph. The Examiner has also maintained the rejection of claims 27-30, which are directed to a single locus conversion of corn plant I450436. In particular, the Examiner has alleged that: (1) the characteristics of the claimed plants are unpredictable and/or not described, (2) the claims encompass genes that have yet to be discovered, and (3) the sequences and/or sources for the numerous examples of single locus traits disclosed in the application have not been described.

a. The claimed subject matter is not unpredictable

With regard to the first point made by the Examiner, it is noted that a "single locus converted (conversion) plant" is defined at page 23, lines 6-12 of the specification as follows:

> [p]lants which are developed by a plant breeding technique called backcrossing wherein essentially all of the desired morphological and physiological characteristics of an inbred are recovered in addition to the characteristics conferred by the single locus transferred into the inbred *via* the backcrossing technique. A single locus may comprise one gene, or in the case of transgenic plants, one or more transgenes integrated into the host genome at a single site (locus).

Therefore, the claimed plants comprising a single locus conversion possess "essentially all of the desired morphological and physiological characteristics of [the single gene converted plant]". Similarly, claim 16 is directed to a corn plant that is capable of expressing all the physiological

and morphological characteristics of the corn variety I450436 which is further defined as comprising a nuclear or cytoplasmic gene conferring male sterility. The Examiner's comments with regard to various allegedly unknown characteristics are thus outside the scope of the claims. With regard to the claimed subject matter, Appellants have more than adequately described such a plant that comprises essentially all of the desired morphological and physiological characteristics of corn plant I450436 by way of the description and deposit of I450436 alone, not to mention the additional description provided. To hold otherwise would be to limit Appellants to that subject matter described *ipsis verbis* in the specification. This position is expressly contradictory to Federal Circuit precedent. *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (stating that the written description requirement does not require an applicant to "describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (citations omitted)).

b. The Examiner has applied the written description requirement with respect to unclaimed subject matter

With respect to the Examiner's allegation that the claims encompass genes that have yet to be discovered, it is noted that Appellants ***do not claim undiscovered genes***. The claimed subject matter is the corn variety I450436 comprising a nuclear or cytoplasmic gene conferring male sterility or a single locus conversion. Nuclear and cytoplasmic genes conferring male sterility and introduction of these genes into corn varieties have been well known for many years (see U.S. Patent No. 3,861,709; U.S. Patent No. 3,710,511; U.S. Patent No. 4,654,465; U.S. Patent No 5,625,132; U.S. Patent No. 4,727,219; U.S. Patent No. 5,530,191; U.S. Patent No. 5,689,041; U.S. Patent No. 5,741,684; and U.S. Patent No. 5,684,242). Further, any single locus conversion may be introduced into corn variety I450436 to produce the single locus conversions

in claims 27-30. The fact that a given gene could be isolated in the future and introduced as a single locus conversion is irrelevant – the new gene is not claimed *per se*, a single locus conversion of corn plant I450436 is claimed. Under the reasoning of the Examiner, essentially any claim could be read to encompass subject matter yet to be invented and therefore not be described. A claim to a corn plant transformed with a *Bacillus thuringiensis* gene would be invalid because it would encompass corn varieties yet to be discovered. A claim to a given gene operably linked to a regulatory element would be invalid because as yet to be isolated regulatory elements would be encompassed. Nearly any biotechnological invention could be viewed this way applying the Examiner's reasoning. However, it is not any given single locus that is claimed, it is a corn plant of corn variety I450436 which comprises a single locus that has been claimed.

c. Appellants have disclosed numerous single locus traits and such traits were well known to those of skill in the art

The Examiner alleges that Appellants have not described the full genus of loci for preparation of converted plants. However, the Examiner has ignored Appellants evidence submitted in the prior response to office action and also recited in the specification showing numerous single locus traits that were described.

Among just the examples in the specification recited with a publication reference or patent number are the following (see specification at pages 29-34): genes conferring male sterility (U.S. Patent No. 3,861,709, U.S. Patent No. 3,710,511, U.S. Patent No. 4,654,465, U.S. Patent No 5,625,132, and U.S. Patent No. 4,727,219, incorporated by reference); male-sterility restorer genes (U.S. Patent Nos. 5,530,191, 5,689,041, 5,741,684, and 5,684,242, incorporated by reference); a herbicide resistant EPSPS mutation termed *aroA* (U.S. Patent 4,535,060); and a

mutant maize gene encoding a protein with amino acid changes at residues 102 and 106 (PCT Publication WO 97/04103).

The single locus traits are also described by way of PCT Application Publ. WO 95/06128, which was specifically incorporated by reference at page 31 of the specification. Examples of some of the single locus traits described in WO 95/06128, including any associated phenotype and publication reference given, are as follows:

the uidA gene from *E. Coli* encoding β-glucuronidase (GUS) (cells expressing *uidA* produce a blue color when given the appropriate substrate, Jefferson, R.A. 1987. *Plant Mol. Biol. Rep* 5: 387-405); the *bar* gene from *Streptomyces hygroscopicus* encoding phosphinothricin acetyltransferase (PAT) (cells expressing PAT are resistant to the herbicide Basta, White, J., Chang, S.-Y.P., Bibb, M.J., and Bibb, M.J. 1990. *Nucl. Ac. Research* 18: 1062); the *lux* gene from firefly encoding luciferase (cells expressing *lux* emit light under appropriate assay conditions, deWet, J.R., Wood, K.V., DeLuca, M., Helinski, D.R., Subramani, S. 1987. *Mol. Cell. Biol.* 7: 725-737); the *dhfr* gene from mouse encoding dihydrofolate reductase (DHFR) (cells expressing *dhfr* are resistant to methotrexate; Eichholtz, D.A., Rogers, S.G., Horsch, R.B., Klee, H.J., Hayford, M., Hoffman, N.L., Bradford, S.B., Fink, C., Flick, J., O'Connell, K.M., Frayley, R.T. 1987. *Somatic Cell Mol. Genet.* 13: 67-76); the *neo* gene from *E.Coli* encoding aminoglycoside phosphotransferase (APH) (cells expressing *neo* are resistant to the aminoglycoside antibiotics; Beck, E., Ludwig, G., Auerswald, E.A., Reiss, B., Schaller, H. 1982. *Gene* 19: 327-336); the *amp* gene from *E. Coli* encoding β-lactamase (cells expressing β-lactamase produce a chromogenic compound when given the appropriate substrate; Sutcliffe, J.G. 1978. *Proc. Nat. Acad. Sci.* USA 75: 3737-3741); the *xylE* gene from *Ps. putida* encoding catechol dihydroxygenase (cells expressing *xylE* produce a chromogenic compound when given the appropriate substrate; Zukowsky *et al.* 1983. *Proc. Nat. Acad. Sci.* USA 80: 1101-1105); the R,C1 and B genes from maize encode proteins that regulate anthocyanin biosynthesis in maize (Goff, S., Klein, T., Ruth, B., Fromm, M., Cone, K., Radicella, J., Chandler, V. 1990. *EMBO J.:* 2517-2522); the ALS gene from *Zea mays* encoding acetolactate synthase and mutated to confer resistance to sulfonylurea herbicides (cells expressing ALS are resistant to the herbicide; Gleen. Yang, L.Y., Gross, P.R., Chen, C.H., Lissis, M. 1992. *Plant Molecular Biology* 18: 1185-1187); the proteinase inhibitor II gene from potato and tomato (plants expressing the proteinase inhibitor II gene show increased resistance to insects; potato - Graham, J.S., Hall, G., Pearce, G., Ryan, C.A. 1986 *Mol. Cell. Biol.* 2: 1044-1051; tomato - Pearce, G., Strydom, D., Johnson, S., Ryan, C.A. 1991. *Science* 253: 895-898); the *Bt* gene from *Bacillus thuringensis* berliner 1715 encoding a protein that is toxic to insects (this gene is the coding sequence of *Bt* 884 modified in two regions for improved expression in plants; Vaeck, M., Reynaerts, A., Hofte, H., Jansens, S., DeBeuckeleer, M., Dean, C., Aeabeau, M., Van Montagu, M., and Leemans, J. 1987. *Nature* 328: 33-37); the *bxn* gene from *Klebsiella ozaeneae* encoding a nitrilase enzyme specific for the herbicide bromoxynil (cells expressing this gene are resistant to the herbicide bromoxynil; Stalker, D.m., McBride, K.E., and Malyj, L. *Science* 242: 419-422, 1988); the WGA-A gene encoding wheat germ agglutinin (expression of the WGA-A

gene confers resistance to insects; Smith, J.J., Raikhel, N.V. 1989. *Plant Mol. Biology* 13: 601-603); the *dapA* gene from *E. coli* encoding dihydrodipicolinate synthase (expression of this gene in plant cells produces increased levels of free lysine; Richaud, F., Richaud, C., Rafet, P. and Patte, J.C. 1986. *J. Bacteriol.* 166: 297-300); the *Z10* gene encoding a 10kd zein storage protein from maize (expression of this gene in cells alters the quantities of 10kD Zein in the cells; Kirihara, J.A., Hunsperger, J.P., Mahoney, W.C., and Messing, J. 1988. *Mol. Gen. Genet.* 211: 477-484); the Bt gene cloned from *Bacillus thuringensis* Kurstaki encoding a protein that is toxic to insects (the gene is the coding sequence of the cry IA(c) gene modified for improved expression in plants - plants expressing this gene are resistant to insects; Höfte, H. and Whiteley, H.R., 1989. *Microbiological Reviews.* 53: 242-255); the ALS gene from *Arabidopsis thaliana* encoding a sulfonylurea herbicide resistant acetolactate synthase enzyme (cells expressing this gene are resistant to the herbicide Gleen. Haughn, G.W., Smith, J., Mazur, B., and Somerville, C. 1988. *Mol. Gen. Genet.* 211: 266-271); the *dehl* gene from *Pseudomonas putida* encoding a dehalogenase enzyme (cells expressing this gene are resistant to the herbicide Dalapon; Buchanan-Wollaston, V., Snape, A., and Cannon, F. 1992. *Plant Cell Reports* 11: 627-631); the hygromycin phosphotransferase II gene from *E. coli* (expression of this gene in cells produces resistance to the antibiotic hygromycin. Waldron, C., Murphy, E.B., Roberts, J.L., Gustafson, G.D., Armour, S.L., and Malcolm, S.K. *Plant Molecular Biology* 5: 103-108, 1985); the *mtlD* gene cloned from *E. coli* (the gene encodes the enzyme mannitol-1-phosphate dehydrogenase; Lee and Saier, 1983. *J. of Bacteriol.* 153:685); the HVA-1 gene encoding a Late Embryogenesis Abundant (LEA) protein (the gene was isolated from barley; Dure, L., Crouch, M., Harada, J., Ho, T.-H. D. Mundy, J., Quatrano, R, Thomas, T, and Sung, R., *Plant Molecular Biology* 12: 475-486.

The foregoing represent just some of the single locus coding sequences that were known as of March 2, 1995; more than ***six years prior*** to the filing of the instant application. More than 25 regulatory elements were also described therein, as were numerous transformation vectors comprising combinations of these elements. Appellants could describe many more examples of single locus traits that were well known as of the filing date, and would be glad to do so should the Board find it useful. It thus goes without saying that single locus traits were more than well known to those of skill in the art as of the filing date and were fully described in the specification.

Techniques for the introduction of single locus traits by genetic transformation were further well known to those of skill in the art. Some of the transformation methods for corn that were well known as of the filing date and cited in the specification include the following: electroporation (U.S. Patent No. 5,384,253), microprojectile bombardment (U.S. Patent No.

5,550,318; U.S. Patent No. 5,736,369, U.S. Patent No. 5,538,880; and PCT Publication WO 95/06128), *Agrobacterium*-mediated transformation (U.S. Patent No. 5,591,616 and E.P. Publication EP672752), direct DNA uptake transformation of protoplasts (Omirulleh *et al.*, 1993) and silicon carbide fiber-mediated transformation (U.S. Patent No. 5,302,532 and U.S. Patent No. 5,464,765). Introduction of such traits by conventional breeding was also known. In fact, this is one of the most fundamental procedures in agricultural science, and it has not been alleged that this has not been described.

Appellants have therefore shown possession of the claimed male sterile plants and single locus conversions. Both large numbers of male sterility genes and single locus traits and the associated phenotypes were well known to those of skill in the art. The specification itself defines a single locus converted plant as comprising essentially all of the desired morphological and physiological characteristics of the starting non-converted plant, *e.g.*, I450436. Well more than an adequate number of examples have been provided and were known in the art to satisfy written description. The state of the art must be considered in the written description determination. As such, Appellants respectfully request reversal of the rejection.

2. Hybrid plants recited in claims 24 –26 have been fully described

a. The claimed hybrid plants share the genetic complement of corn variety I450436

Rejected claims 24-26 are directed to hybrid plants and seeds produced with corn plant I450436 as one parent. Appellants have fully described this claimed subject matter in compliance with the written description requirement of 35 U.S.C. §112, first paragraph. As set forth in the breeding history at pages 26-27 of the specification, corn plant I450436 is an inbred corn plant. All of the claimed hybrid plants having I450436 as a parent will therefore contain a copy of the same genome as corn plant I450436. That is, because I450436 is an inbred corn

plant, hybrid corn plants derived therefrom will have as half of their genetic material the same genetic contribution of corn plant I450436, save the possibility of the rare spontaneous mutation or undetected segregating locus. This entire genetic contribution of corn plant I450436 is described in the specification by way of the deposit of seed of corn plant I450436 with the ATCC. *See Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1330 (Fed. Cir. 2002) (holding that a biological deposit constitutes a written description of the deposited material under 35 U.S.C. §112, first paragraph). This represents a description of concrete and identifiable structural characteristics defining the claimed hybrid plants and distinguishing them from other plants in full compliance with the written description requirement.

The Federal Circuit has noted that such shared identifiable structural features are important to the written description requirement. *The Regents of The University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997) (noting that a name alone does not satisfy the written description requirement where "it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, *as one can do with a fully described genus, visualize or recognize the identity of the members of the genus*" (emphasis added)). Here, all of the members of the claimed genus of hybrids having I450436 as one parent share the structural feature of having the genetic complement of I450436. One of skill in the art could thus readily identify the members of the genus. The written description requirement has, therefore, been fully complied with.

b. The shared characteristics of the claimed hybrid plants are readily identified and described in the specification

As set forth above, the claimed F1 hybrid plants having I450436 as one parent will share the same genetic complement received from I450436. This is readily identifiable by genetic

marker analysis, as shown in Tables 6 and 8 of the specification. There shown is the SSR genetic marker profile of corn variety I450436, as well as an the exemplary hybrid plant designated 8018717 that was made using I450436 as one parent. As can be seen, hybrid corn plant 8018717 has the SSR genetic marker profile of I450436, and also includes the genetic markers from the second parent plant used to make the hybrid. The same will be true for any other hybrid plant having I450436 as one parent, save for an occasional difference at a locus due to spontaneous genetic rearrangements, which occur at statistically insignificant frequencies in essentially all organisms.

The second plant that is used to make the claimed hybrid plants is irrelevant, as a hybrid will be produced any time corn plant I450436 is crossed with a second plant. That is, any second plant capable of reproduction may be used to make the hybrid plant. Appellants cannot therefore be said to lack written description for the second genetic complement. This is particularly so given that hundreds or even thousands of different inbred corn lines were well known to those of skill in the art prior to the filing of the instant application, each of which could be crossed to make a hybrid plant within the scope of the claims. This is evidenced by a review of the U.S.P.T.O. patent data website, which reveals more than 300 utility patents issued on different corn varieties issued prior to the filing date of the current application. Any one of these corn plants, or the many hundreds or thousands of other maize plants that were known at the time the application was filed, could be used to produce an F1 hybrid plant having corn variety I450436 as one parent, and each of these would share the genetic complement of I450436.

Written description is reviewed from the perspective of one of skill in the art at the time the application is filed. *Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 863 (Fed. Cir. 1993). The specification need not disclose what is well-known to those skilled in the art and preferably

omits what is well-known and already available to the public. *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991). As ***any*** second plant may be used to produce the claimed hybrid plants and such plants were well known to those of skill in the art, Appellants cannot be said to have not been in possession of the second parent plant. The claimed hybrid corn plants have therefore been described in compliance with 35 U.S.C. §112, first paragraph.

The Examiner attempts to downplay the significance of the genetic marker data given in the specification by stating that some loci may be shared by other plants, that primer sequences are not described or that certain isozyme markers are not informative. However, no effort has been made to show that any substantial number of marker loci actually ***are*** shared by other plants. Further, Appellants do not claim such "other" plants, so this is irrelevant to written description. No basis has been provided to conclude that the claimed hybrid plants are not distinct and clearly identifiable by the genetic marker profile that has been set forth. Regarding the availability of genetic markers, the service that was used to detect SSR markers is commercially available to the public. Further, SSR and any of the other genetic marker systems that are well known to those of skill in the art may potentially be used, as is described on pages 60-61 of the specification. Regardless of whether SSR markers are used, the shared genetic complement of the claimed hybrid plants having corn variety I450436 as one parent distinguishes them. As the entire genome of corn variety I450436 has been described, at least, by way of the seed deposit that has been made, any polymorphic locus could be used including or in addition to the SSR markers shown in Tables 6 and 8.

c. The entire genetic complement of soybean variety 961905802272 is described by way of the proffered deposit of seed

The Examiner alleges that Appellants have not disclosed the genetic complement of this variety that is shared by each of the claimed hybrid plants and seeds. It is thus alleged that the

genetic contribution of variety I450436 could not be distinguished and is not described. This is incorrect, however, as Appellants describe the entire genetic sequence of soybean variety I450436 by way of a deposit of seed of the variety.

The Federal Circuit has recently held that a biological deposit may be used to satisfy written description for nucleic acids, whether the nucleic acid sequence is set forth in the specification or not. Specifically, in *Enzo Biochem, Inc. v. Gen-Probe Inc.*, the patent owner had deposited six strains of *N. gonorrhoeae* and claimed nucleotide sequences hybridizing to the nucleic acids of these strains, but the patent application did not set forth the nucleic acid sequences of these strains in the specification. 296 F.3d 1316, 1328 (Fed. Cir. 2002). The Federal Circuit nonetheless held that "as those bacteria were deposited, their ***bacterial genome is accessible*** and, under our holding today, they are ***adequately described in the specification by their accession numbers***." *Id.* (emphasis added). In its holding, the Federal Circuit considered the burden that would be placed on applicants were they required to sequence each of the strains, noting lower court findings that it would have taken 3,000 scientists a month to sequence the bacterial genome of one strain of *N. gonorrhoeae. Id.* In the instant case, even more effort would be required, as corn is a higher life form with a more complex genome than the bacteria deposited in *Enzo*. The Examiner would nonetheless appear to require this much of Appellants in direct contradiction of *Enzo*.

The fact that the deposit here will be made after the filing date of the application has no bearing on written description, as the Federal Circuit has noted that insertion of an accession number for a deposit after the filing date adds no new matter to a case provided the deposited subject matter is clearly identified in the application. See *In re Lundak*, 773 F.2d 1216, 1217 (Fed. Cir. 1985) ("....an accession number and deposit date add nothing to the written

description of the invention"). Appellants have therefore fully described the shared structure of the claimed hybrid plants at the nucleic acid level and thus have fully complied with 35 U.S.C. §112, first paragraph.

d. The Examiner's allegations that the expression of the genetic complement of corn variety I450436 is unpredictable are inapposite

The Examiner alleges that claimed hybrid plants have not been described despite inheriting the genetic complement of variety I450436 because information is not provided regarding the morphological and physiological traits of the hybrid plants. It is alleged that how the genes that are inherited would be expressed or would interact has not been shown. However, this misses the point that Appellants have gone one step further than morphological and physiological traits by describing the claimed hybrid plants at the genetic level. A better description could not be made than at the genetic level. Morphological and physiological traits, while helpful, are also subject to environmental variation and require subjective gradations. Genetic testing goes to the source of traits and yields concrete values.

The law further makes no distinctions regarding the manner in which applicants choose to describe claimed compositions. Rather, an applicant must merely describe the claimed subject matter by "whatever characteristics sufficiently distinguish it." *Amgen v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206 (Fed. Cir. 1991). Here, Appellants have described the genetic complement of parent plant I450436 that will be comprised in the claimed hybrid plants. This has been achieved using the SSR and isozyme genetic marker profiles given in tables 6-9 of the specification. Indeed, Appellants describe the entire genetic complement of parent plant I450436 by way of a seed deposit made with the ATCC, as set forth above, as described above. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1330 (Fed. Cir. 2002).

e. Appellants fully describe an exemplary hybrid made using inbred I450436

Further description of claimed hybrid plants is also provided in the specification by way of a detailed description of hybrid 8018717, which was produced with I450436 as one inbred parent. This plant is representative of hybrids produced using I450436 as one parent, each of which comprise the genetic complement of the parent corn plant as set forth above. Table 4 of the specification gives the performance characteristics for 8018717 and provides comparisons against other hybrid varieties. In Table 5, the morphological traits of 8018717 are given. The SSR and isozyme marker profiles for hybrid 8018717 are given in Tables 8 and 9, respectively. This information, combined with the descriptions of I450436 in the specification and the shared structure among hybrids having corn plant I450436 as a parent, is more than adequate to describe the claimed subject matter.

3. The rejection of claim 31 has been improperly issued and maintained

a. The rejection of claim 31 is improper

Claim 31 reads as follows:

31. A method of producing an inbred corn plant derived from the corn variety I450436, the method comprising the steps of:

(a) preparing a progeny plant derived from corn variety I450436 by crossing a plant of the corn variety I450436 with a second corn plant, wherein a sample of the seed of the corn variety I450436 was deposited under ATCC Accession No. PTA-4495;

(b) crossing the progeny plant with itself or a second plant to produce a seed of a progeny plant of a subsequent generation;

(c) growing a progeny plant of a subsequent generation from said seed and crossing the progeny plant of a subsequent generation with itself or a second plant; and

(d) repeating steps (b) and (c) for an addition 3-10 generations to produce an inbred corn plant derived from the corn variety I450436.

The position of the Examiner is that each product produced at any intermediate or penultimate step of the method is not adequately described. However, what is required to meet the written description requirement is that an Applicant show that he or she was in possession of the ***claimed***

invention. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). Here, a process is claimed, not a product of a process, and thus the steps of that process must be described, not intermediate or final products of the steps. The starting materials for the process must also be provided, otherwise the process could not be completed. However, the only starting materials required are corn variety I450436, which the Examiner does not allege to have not been described, and ***any*** second corn plant. As set forth above, corn plants were well known, and this has also therefore been fully described.

With respect to the steps, these have been fully set forth in the claim. It has not been alleged that any essential steps are absent. All that is required to complete the claimed method is to cross the corn variety I450436 or a product that is produced by any preceding step according to the steps given. All of the starting materials for any step within the method are either (1) corn variety I450436, (2) any second corn plant, or (3) a corn plant that is produced by following a preceding method step. The method has therefore been fully described.

It is also noted that corn breeding is well known to those of skill in the art. Without it, there would not be commercial corn varieties, which are typically sold as hybrids produced by crossing two inbred varieties. This is evidenced by the more than 300 issued patents to inbred maize varieties discussed above, given that inbred plants are not produced without multiple generations of intentional self-fertilization breeding steps. All of the steps recited in claim 31 are typical of the process used for the production of new corn varieties, save for the point of novelty, corn variety I450436. This is evidenced in the breeding history for the production of corn variety I450436, which is given in the specification. The specification also describes methods for producing new corn varieties in the review of related art, for example, at pages 2-4 of the application.

In conclusion, all steps of the claimed process have been recited, all starting materials have been fully described, and methods of producing new corn varieties were well known to those of skill in the art. Claim 31 has therefore been fully described in compliance with 35 U.S.C. §112, first paragraph. Reversal of the rejection is thus respectfully requested.

b. The Examiner has failed to adequately support the rejections

The Examiner has cited the Written Description Guidelines, Fed. Reg. Vol. 66, pp1099-1111 (Jan. 5, 2001), as allegedly supporting the rejection. A review of this section finds no support for the position taken. It is respectfully submitted that the Guidelines have been applied by the Examiner in the context of product-by-process claims, not process claims. Nowhere does the comment state that process and composition claims are analyzed in the same manner. Indeed, Appellants note that the initial analysis of written description set forth under the Guidelines involves "(i) Determine whether the application as filed describes the complete structure (***or*** acts of a ***process***) of the claimed invention as a whole." (emphasis added). Elsewhere in the guidelines the same distinction is made. The Guidelines therefore fail to support and contradict the position taken by the Examiner.

Findings of fact and conclusions of law by the U.S. Patent and Trademark Office must be made in accordance with the Administrative Procedure Act ("APA"). 5 U.S.C. § 706(A), (E), 1994; *see also In re Zurko,* 59 USPQ 2d 1693 (Fed. Cir. 2001). In particular, the Federal Circuit has held that findings by the Board of Patent Appeals and Interferences must be supported by "substantial evidence" within the record pursuant to the APA. *See In re Gartside*, 203 F.3d 1305, 1314-15 (Fed. Cir. 2000). Thus, an Examiner's position on Appeal must be supported by "substantial evidence" within the record in order to be upheld by the Board of Patent Appeals and Interferences. As demonstrated above, the current rejections are unsupported in fact or law.

The standards of the APA have therefore not been met and reversal of the rejection is thus respectfully requested.

C. The Claims Are Enabled Under 35 U.S.C. §112, First Paragraph

1. Male Sterile Plants and Conversions of Variety I450436 are Enabled

The Examiner rejects claims 16 and 24-31 under 35 U.S.C. §112, first paragraph as not being enabled. Claims 16 and 27-30 are directed to corn plants of the claimed variety which comprise a single locus conversion or a nuclear or cytoplasmic gene conferring male sterility. The Examiner alleges that no guidance has been provided for creation of such plants. However, this ignores the working example in the specification describing a single locus conversion that was made with a proprietary corn variety. This example gives the breeding history of the conversion that was made, including a description of seven backcrosses. The example describes exactly the type of process one of skill in the art could use to prepare conversions of the instant variety. The specification provides in great detail further guidance for creation of converted plants at pages 30-34. The techniques recited are also all well known in the art (*e.g.*, Poehlman *et al.*, 1995; Fehr, 1987; Sprague and Dudley, 1988).

With regard to creation of male sterile plants, this is also a technique that has been well-known for decades. This is evidenced by the numerous issued patents for creation of male sterile plants (see U.S. Patent No. 3,861,709; U.S. Patent No. 3,710,511; U.S. Patent No. 4,654,465; U.S. Patent No 5,625,132; U.S. Patent No. 4,727,219; U.S. Patent No. 5,530,191; U.S. Patent No. 5,689,041; U.S. Patent No. 5,741,684; and U.S. Patent No. 5,684,242, incorporated by reference).

The only basis alleged by the Examiner for the rejection is several references said to show the difficulty of making male sterile or single locus converted plants. However, these

references have not been shown to have any relevance to ***corn*** plants. Hunsperger deals with petunias; Kraft with sugar beets and Eshed with Tomatoes. The relevance of the references to the claimed invention has therefore not been established, as is specifically required to demonstrate a *prima facie* case of non-enablement.

Corn breeding is extremely advanced and well known in the art as evidenced by the descriptions in the specification and references cited therein. This is due in large part to the fact that corn is one of the world's major food crops and largest seed crops. As explained in the specification, North American farmers alone plant ***tens of millions of acres*** of corn at the present time and there are ***extensive national and international commercial corn breeding*** programs. It is respectfully submitted that this is not true of petunias, sugar beets and tomatoes.

The Examiner has also not provided any basis other than opinion to suggest why the genetics of any of petunias, sugar beets or tomatoes are relevant to corn. Each of these plants are widely genetically diverged from maize – they are each classified as dicotyledonous plants whereas maize is a monocotyledonous plants. This distinction was noted by the Federal Circuit in *Plant Genetic Systems v. DeKalb Genetics Corp.*, in which a finding on non-enablement was affirmed because the claims read on both monocotyledonous and dicotyledonous plants, but were only enabled for dicotyledonous plants. 315 F.3d 1335 (Fed. Cir. 2003).

It therefore appears that the Examiner has improperly placed the burden to show enablement on Appellants. The indication that the references concerning petunias, sugar beets and tomatoes apply to corn is made without any support. At the same time, the Examiner attempts to require Appellants to show why this is not true. While Appellants have nonetheless done so, it is respectfully notes that it is the ***Office*** that bears the burden of supporting its rejections. Findings of fact and conclusions of law by the U.S. Patent and Trademark Office

must be made in accordance with the Administrative Procedure Act ("APA"). 5 U.S.C. § 706(A), (E), 1994; *see also In re Zurko,* 59 USPQ 2d 1693 (Fed. Cir. 2001). In particular, the Federal Circuit has held that findings by the Board of Patent Appeals and Interferences must be supported by "substantial evidence" within the record pursuant to the APA. *See In re Gartside,* 203 F.3d 1305, 1314-15 (Fed. Cir. 2000). Thus, an Examiner's position on Appeal must be supported by "substantial evidence" within the record in order to be upheld by the Board of Patent Appeals and Interferences. The current rejections are unsupported as required by the APA and contrary to the evidence submitted by Appellants.

In view of Appellants example, detailed teaching in the specification and the failure to provide any basis to doubt the enablement of the claims, Appellants respectfully request that the rejection be reversed.

2. Production of Hybrid Plants is Enabled

Claims 24-26 are directed to hybrid corn seeds and plants grown therefrom which have the claimed variety as one parent. Appellants specification describes the creation of hybrid plant 8018717, which was produced with I450436 as one inbred parent. This working example provides a full enablement of the claims and no basis has been provided to conclude otherwise. The method used to make this plant, is exactly the same as would be used to make any other hybrid plant with I450436 as one inbred parent, because the method only requires crossing I450436 to ***any second plant.*** This is because a hybrid plant is produced anytime the claimed variety is crossed with a second, different corn plant. Therefore, all that is required to enable the production on hybrid corn plants is that variety I450436 be fertile, which it is as evidenced by the working example described above. The Examiner therefore provides no basis to doubt this enablement.

With respect to availability of second parents, ***any second, different corn plant*** crossed to variety I450436 will produce the recited hybrid plants. There is therefore absolutely no basis for the enablement rejection. For the rejection to be supportable, one of skill in the art would have to be unable to obtain ***any*** second corn plant. However, thousands of corn varieties are known to those of skill in the art. More than 300 utility patents have been issued for corn varieties. A person can literally go to the local nursery or garden supply store and purchase such corn varieties. The Maize Genetics Cooperation Stock Center alone, which is supported by the U.S. Department of Agriculture and provides seed to the public, claims to have a collection approaching 80,000 individually pedigreed maize samples (see. http://w3.ag.uiuc.edu/maize-coop/mgc-info.html). There is, therefore, no basis to allege non-enablement of the full scope of the claims.

3. Claim 31 is Enabled

With regard to claim 31, all that is required to complete the method is for the claimed variety to be fertile and for one of skill in the art to follow the recited breeding steps. ***Any second corn plant*** may be employed in the method together with variety I450436. What other plant or plants one chooses to cross with the claimed variety is therefore ***completely irrelevant to enablement***, as any fertile corn plant could be used to produce an inbred corn plant derived from the corn variety I450436. Further, the breeding steps recited are well known and fully described in the specification (see pages 2-5 and 50-53 of the specification). Enablement only requires that one of skill in the art be able to ***make and use the claimed invention*** without undue experimentation. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The specification has done this and thus fully meets the requirement.

In view of the foregoing reversal of the rejection is respectfully requested.

D. The Rejection Under 35 U.S.C. §102 is Improper

The Action has rejected claim 31 under 35 U.S.C. §102 as allegedly being anticipated. The position of the Examiner is that the claim is anticipated because multiple generations of breeding would cause the resultant product to "lose the genetic material from the starting material and be indistinguishable from the prior art plant."

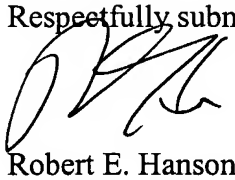
The rejection cannot survive even a cursory review. Claim 31 is a process claim that requires in step (a) "crossing a plant of the corn variety I450436 with a second corn plant." The Examiner has already acknowledged that corn variety I450436 is novel and nonobvious based on the lack of rejection of claim 1-15. All elements of claim 31 are therefore neither taught nor suggested by the prior art. The claim may therefore not be rejected under §102.

In view of the foregoing, reversal of the rejection is respectfully requested.

X. CONCLUSION

It is respectfully submitted, in light of the above, none of the pending claims lack written description. Therefore, Appellants request that the Board reverse the pending grounds for rejection.

Respectfully submitted,



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Date: November 24, 2003

APPENDIX 1: CLAIMS ON APPEAL

16. The corn plant of claim 15, further comprising a nuclear or cytoplasmic gene conferring male sterility.

24. Hybrid corn seed produced by the process of claim 23.

25. A hybrid corn plant produced by growing a seed produced by the process of claim 23.

26. The hybrid corn plant of claim 25, wherein the plant is a first generation (F_1) hybrid corn plant.

27. The corn plant of claim 5, further defined as having a genome comprising a single locus conversion.

28. The corn plant of claim 27, wherein the single locus was stably inserted into a corn genome by transformation.

29. The corn plant of claim 27, wherein the locus is selected from the group consisting of a dominant allele and a recessive allele.

30. The corn plant of claim 27, wherein the locus confers a trait selected from the group consisting of herbicide tolerance; insect resistance; resistance to bacterial, fungal, nematode or viral disease; yield enhancement; waxy starch; improved nutritional quality; enhanced yield stability; male sterility and restoration of male fertility.

31. A method of producing an inbred corn plant derived from the corn variety I450436, the method comprising the steps of:

(a) preparing a progeny plant derived from corn variety I450436 by crossing a plant of the corn variety I450436 with a second corn plant, wherein a sample of the seed of the corn variety I450436 was deposited under ATCC Accession No. PTA-4495;

(b) crossing the progeny plant with itself or a second plant to produce a seed of a progeny plant of a subsequent generation;

(c) growing a progeny plant of a subsequent generation from said seed and crossing the progeny plant of a subsequent generation with itself or a second plant; and

(d) repeating steps (b) and (c) for an addition 3-10 generations to produce an inbred corn plant derived from the corn variety I450436.

APPENDIX 2: PENDING CLAIMS

1. A seed of the corn variety I450436, wherein a sample of the seed of the corn variety I450436 was deposited under ATCC Accession No. PTA-4495.

2. A population of seed of the corn variety I450436, wherein a sample of the seed of the corn variety I450436 was deposited under ATCC Accession No. PTA-4495.

3. The population of seed of claim 2, further defined as an essentially homogeneous population of seed.

4. The population of seed of claim 2, further defined as essentially free from hybrid seed.

5. A corn plant produced by growing a seed of the corn variety I450436, wherein a sample of the seed of the corn variety I450436 was deposited under ATCC Accession No. PTA-4495.

6. The corn plant of claim 5, having:
   (a) an SSR profile in accordance with the profile shown in Table 5; or
   (b) an isozyme typing profile in accordance with the profile shown in Table 6.

7. A plant part of the corn plant of claim 5.

8. The plant part of claim 7, further defined as pollen.

9. The plant part of claim 7, further defined as an ovule.

10. The plant part of claim 7, further defined as a cell.

11. The plant part of claim 10, wherein said cell is further defined as having :
   (a) an SSR profile in accordance with the profile shown in Table 5; or
   (b) an isozyme typing profile in accordance with the profile shown in Table 6.

12. A seed comprising the cell of claim 10.

13. A tissue culture comprising the cell of claim 10.

14. An essentially homogeneous population of corn plants produced by growing the seed of the corn variety I450436, wherein a sample of the seed of the corn variety I450436 was deposited under ATCC Accession No. PTA-4495.

15. A corn plant capable of expressing all the physiological and morphological characteristics of the corn variety I450436, wherein a sample of the seed of the corn variety I450436 was deposited under ATCC Accession No. PTA-4495.

16. The corn plant of claim 15, further comprising a nuclear or cytoplasmic gene conferring male sterility.

17. (A tissue culture of regenerable cells of a plant of corn variety I450436, wherein the tissue is capable of regenerating plants capable of expressing all the physiological and morphological characteristics of the corn variety I450436, wherein a sample of the seed of the corn variety I450436 was deposited under ATCC Accession No. PTA-4495.

18. The tissue culture of claim 17, wherein the regenerable cells comprise cells derived from embryos, immature embryos, meristematic cells, immature tassels, microspores, pollen, leaves, anthers, roots, root tips, silk, flowers, kernels, ears, cobs, husks, or stalks.

19. The tissue culture of claim 18, wherein the regenerable cells comprise protoplasts or callus cells.

20. A corn plant regenerated from the tissue culture of claim 17, wherein the corn plant is capable of expressing all of the physiological and morphological characteristics of the corn variety designated I450436, wherein a sample of the seed of the corn variety I450436 was deposited under ATCC Accession No. PTA-4495.

21. A process of producing corn seed, comprising crossing a first parent corn plant with a second parent corn plant, wherein one or both of the first or the second parent corn plant is a plant of the corn variety I450436, wherein a sample of the seed of the corn variety I450436 was deposited under ATCC Accession No. PTA-4495, wherein seed is allowed to form.

22. The process of claim 21, further defined as a process of producing F1 hybrid corn seed, comprising crossing a first inbred corn plant with a second, distinct inbred corn plant, wherein the first or second inbred corn plant is a plant of the corn variety I450436, wherein a sample of the seed of the corn variety I450436 was deposited under ATCC Accession No. PTA-4495.

23. The process of claim 22, wherein crossing comprises the steps of:

(a) planting the seeds of first and second inbred corn plants;

(b) cultivating the seeds of said first and second inbred corn plants into plants that bear flowers;

(c) preventing self pollination of at least one of the first or second inbred corn plant;

(d) allowing cross-pollination to occur between the first and second inbred corn plants; and

(e) harvesting seeds on at least one of the first or second inbred corn plants, said seeds resulting from said cross-pollination.

24. Hybrid corn seed produced by the process of claim 23.

25. A hybrid corn plant produced by growing a seed produced by the process of claim 23.

26. The hybrid corn plant of claim 25, wherein the plant is a first generation (F_1) hybrid corn plant.

27. The corn plant of claim 5, further defined as having a genome comprising a single locus conversion.

28. The corn plant of claim 27, wherein the single locus was stably inserted into a corn genome by transformation.

29. The corn plant of claim 27, wherein the locus is selected from the group consisting of a dominant allele and a recessive allele.

30. The corn plant of claim 27, wherein the locus confers a trait selected from the group consisting of herbicide tolerance; insect resistance; resistance to bacterial, fungal, nematode or viral disease; yield enhancement; waxy starch; improved nutritional quality; enhanced yield stability; male sterility and restoration of male fertility.

31. A method of producing an inbred corn plant derived from the corn variety I450436, the method comprising the steps of:

(a) preparing a progeny plant derived from corn variety I450436 by crossing a plant of the corn variety I450436 with a second corn plant, wherein a sample of the seed of the corn variety I450436 was deposited under ATCC Accession No. PTA-4495;

(b) crossing the progeny plant with itself or a second plant to produce a seed of a progeny plant of a subsequent generation;

(c) growing a progeny plant of a subsequent generation from said seed and crossing the progeny plant of a subsequent generation with itself or a second plant; and

(d) repeating steps (b) and (c) for an addition 3-10 generations to produce an inbred corn plant derived from the corn variety I450436.

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: James Larkins	Group Art Unit: 1632
Serial No.: 10/077,591	Examiner: Fox, D.
Filed: February 15, 2002	Atty. Dkt. No.: DEKA:299US
For: PLANTS AND SEEDS OF CORN VARIETY I450436	

BRIEF ON APPEAL

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellants hereby submit an original and two copies of this Appeal Brief. The fee for filing this Appeal Brief is attached hereto. The date for filing the instant Brief is November 24, 2003, based on the receipt of the Notice of Appeal by the Patent and Trademark Office on September 22, 2003. No additional fees are believed due in connection with the instant paper. However, should any fees be due, the Commissioner is authorized to withdraw the appropriate fee from Fulbright & Jaworski L.L.P. Deposit Account No. 50-1212/DEKA:299US. Please date stamp and return the enclosed postcard to evidence receipt of this document.

I. REAL PARTIES IN INTEREST

The real party in interest is Monsanto Company, the parent of wholly-owned subsidiary DeKalb Genetics Corporation, the assignee of this application.

II. RELATED APPEALS AND INTERFERENCES

Appeals were filed in U.S. Patent Application Ser. No. 09/772,520; U.S. Patent Application Ser. No. 09/788,334; U.S. Patent Application Ser. No. 09/606,808; and U.S. Patent Application Ser. No. 10/077,589, which are also directed to inbred corn plants and therefore may have a bearing on the Board's decision in the pending appeal.

III. STATUS OF THE CLAIMS

Claims 1-31 were filed with the application and were pending at the time of the final Office Action. Claims 1-15 and 17-23 were allowed in the final Office Action and claims 16 and 24-31 were rejected. No amendments have been made subsequent to the final Office Action. Claims 1-31 are currently pending. The rejection of claims 16 and 24-31 is the subject of the instant Appeal. A copy of the appealed claims is attached hereto as Appendix 1. A copy of the pending claims is attached as Appendix 2.

IV. STATUS OF AMENDMENTS

No amendments have been made subsequent to the final Office Action.

V. SUMMARY OF THE INVENTION

The invention relates to the novel inbred corn plant designated I450436 and seeds or populations of seed thereof. Specification at page 5, lines 3-19. The invention also relates to male sterile and single locus converted plants of I450436. Specification at page 6, lines 6-27. The invention further relates to methods for breeding I450436 with other corn plants, and hybrid plants produced thereby. Specification from page 7, line 15 to page 9, line 12.

VI. ISSUES ON APPEAL

(1) Were claims 16 and 27-30 properly rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out the subject matter which applicants regard as the invention?

(2) Were claims 16 and 24-31 properly rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to convey that the applicants were in possession of the claimed invention?

(3) Were claims 16 and 24-31 properly rejected under 35 U.S.C. §112, first paragraph, as not being enabled?

(4) Is claim 31 properly rejected under 35 U.S.C. §102 as being anticipated?

VII. GROUPING OF THE CLAIMS

Claim 16 is directed to a corn plant capable of expressing all the physiological and morphological characteristics of the corn variety I450436 that further comprises a nuclear or cytoplasmic gene conferring male sterility. None of the other claims are directed to this subject matter and thus distinct issues are raised under 35 U.S.C. §112, first paragraph. The claim therefore stands or falls alone. Claims 24-26 are directed to hybrid plants produced by crossing the inbred corn plant of the invention. None of the other claims are directed to this subject matter and thus distinct issues are raised by the claims under 35 U.S.C. §112, first paragraph. Claims 24-26 therefore stand or fall together but separately from the remaining claims. Claims 27-30 are directed to a corn plant of variety I450436 that comprises a single locus conversion. None of the other claims are directed to this subject matter and thus distinct issues are raised by the claims under 35 U.S.C. §112, first paragraph. Claims 27-30 therefore stand or fall together but separately from the remaining claims. Claim 31 is directed to a method of producing an

inbred corn plant derived from the corn variety I450436. Distinct issues are raised by the claim under 35 U.S.C. §112, first paragraph. Claim 31 therefore stands or falls separately from the remaining claims.

VIII. SUMMARY OF THE ARGUMENT

The indefiniteness rejections fail because the metes and bounds of each of the rejected claims are clear to one of skill in the art in view of the well known meaning of the terms used and the language of the claims.

The written description rejections fail because the claimed subject matter has been fully described. Each of the claimed hybrid plants and seeds having inbred corn plant I450436 as one parent have as half of their genome the same genetic contribution from I450436, given that corn plant I450436 is inbred. This structural characteristic is readily detectable and thus defines the claimed plants. The claimed plants are produced using any second plant, thus written description with regard to the second parent is satisfied based on the countless corn varieties known to those of skill in the art, including the more than 300 corn varieties for which utility patents have previously been issued. Methods of crossing the claimed corn variety have been fully described in the recited steps, and such corn breeding steps were well known in the art. Single locus conversions of I450436 were also fully described, in that well more than a representative collection of single locus conversion traits are described in the specification and were well known to those of skill in the art. The single locus conversion traits themselves are further not being claimed, rather it is corn plant I450436 comprising a single locus conversion that is claimed. The written description requirement has thus been fully satisfied.

The enablement rejections fail because Appellants working examples and descriptions in the specification fully enable the claimed subject matter. The Examiner has improperly

disregarded this evidence and failed to support the rejections in contradiction to the standards of the APA.

The anticipation rejection of claim 31 fails because step (a) of the claimed method requires the use of corn variety I450436. The Examiner has acknowledged the novelty and nonobviousness of corn variety I450436 based on the lack of rejection of claims 1-15. The prior art therefore fails to teach or suggest all elements of the claim.

IX. ARGUMENT

The Examiner has finally rejected claims 16 and 27-30 as being indefinite under 35 U.S.C. §112, second paragraph; claims 16 and 24-31 as lacking an adequate written description in the specification under 35 U.S.C. §112, first paragraph; and claims 16 and 24-31 as lacking enablement under 35 U.S.C. §112, first paragraph. Appellants respectfully request that the Board reverse the rejections for the reasons set forth below.

A. The Claims Are Definite Under 35 U.S.C. §112, Second Paragraph

The Examiner rejects claims 16 and 27-30 as broadening the scope of the claims from which they depend. Claim 16 depends from claim 15 and therefore incorporates all of the limitations of claim 15, but further specifies the added characteristic of male sterility. In particular, the claim is directed to the corn plant of claim 15 "further comprising a nuclear or cytoplasmic gene conferring male sterility." Therefore an additional limitation not required by claim 15 is specified. Similarly, claim 27 is directed to the corn plant of claim 5 "further defined as having a genome comprising a single locus conversion." Again, the claim specifies an additional characteristic relative to the main claim while including all of the limitations. Therefore, both claims (1) contain a reference to the parent claim from which they depend, (2) contain a further limitation of the main claim, and (3) incorporate all elements of the claim from

which they depend. The claims are therefore in proper dependent form pursuant to 37 C.F.R. §1.75(c) and are fully definite. Reversal of the rejection is therefore respectfully requested.

B. The Written Description Rejection of Claims 16 and 24-31 Under 35 U.S.C. §112, First Paragraph Is Improper

1. Male Sterile and Single Locus Converted Plants Are Described

The Examiner rejects claim 16, which is directed to the corn plant of claim 15 further comprising a nuclear or cytoplasmic gene conferring male sterility, as lacking written description under 35 U.S.C. §112, first paragraph. The Examiner has also maintained the rejection of claims 27-30, which are directed to a single locus conversion of corn plant I450436. In particular, the Examiner has alleged that: (1) the characteristics of the claimed plants are unpredictable and/or not described, (2) the claims encompass genes that have yet to be discovered, and (3) the sequences and/or sources for the numerous examples of single locus traits disclosed in the application have not been described.

a. The claimed subject matter is not unpredictable

With regard to the first point made by the Examiner, it is noted that a "single locus converted (conversion) plant" is defined at page 23, lines 6-12 of the specification as follows:

> [p]lants which are developed by a plant breeding technique called backcrossing wherein essentially all of the desired morphological and physiological characteristics of an inbred are recovered in addition to the characteristics conferred by the single locus transferred into the inbred *via* the backcrossing technique. A single locus may comprise one gene, or in the case of transgenic plants, one or more transgenes integrated into the host genome at a single site (locus).

Therefore, the claimed plants comprising a single locus conversion possess "essentially all of the desired morphological and physiological characteristics of [the single gene converted plant]". Similarly, claim 16 is directed to a corn plant that is capable of expressing all the physiological

and morphological characteristics of the corn variety I450436 which is further defined as comprising a nuclear or cytoplasmic gene conferring male sterility. The Examiner's comments with regard to various allegedly unknown characteristics are thus outside the scope of the claims. With regard to the claimed subject matter, Appellants have more than adequately described such a plant that comprises essentially all of the desired morphological and physiological characteristics of corn plant I450436 by way of the description and deposit of I450436 alone, not to mention the additional description provided. To hold otherwise would be to limit Appellants to that subject matter described *ipsis verbis* in the specification. This position is expressly contradictory to Federal Circuit precedent. *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (stating that the written description requirement does not require an applicant to "describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (citations omitted)).

b. The Examiner has applied the written description requirement with respect to unclaimed subject matter

With respect to the Examiner's allegation that the claims encompass genes that have yet to be discovered, it is noted that Appellants ***do not claim undiscovered genes***. The claimed subject matter is the corn variety I450436 comprising a nuclear or cytoplasmic gene conferring male sterility or a single locus conversion. Nuclear and cytoplasmic genes conferring male sterility and introduction of these genes into corn varieties have been well known for many years (see U.S. Patent No. 3,861,709; U.S. Patent No. 3,710,511; U.S. Patent No. 4,654,465; U.S. Patent No 5,625,132; U.S. Patent No. 4,727,219; U.S. Patent No. 5,530,191; U.S. Patent No. 5,689,041; U.S. Patent No. 5,741,684; and U.S. Patent No. 5,684,242). Further, any single locus conversion may be introduced into corn variety I450436 to produce the single locus conversions

in claims 27-30. The fact that a given gene could be isolated in the future and introduced as a single locus conversion is irrelevant – the new gene is not claimed *per se*, a single locus conversion of corn plant I450436 is claimed. Under the reasoning of the Examiner, essentially any claim could be read to encompass subject matter yet to be invented and therefore not be described. A claim to a corn plant transformed with a *Bacillus thuringiensis* gene would be invalid because it would encompass corn varieties yet to be discovered. A claim to a given gene operably linked to a regulatory element would be invalid because as yet to be isolated regulatory elements would be encompassed. Nearly any biotechnological invention could be viewed this way applying the Examiner's reasoning. However, it is not any given single locus that is claimed, it is a corn plant of corn variety I450436 which comprises a single locus that has been claimed.

c. Appellants have disclosed numerous single locus traits and such traits were well known to those of skill in the art

The Examiner alleges that Appellants have not described the full genus of loci for preparation of converted plants. However, the Examiner has ignored Appellants evidence submitted in the prior response to office action and also recited in the specification showing numerous single locus traits that were described.

Among just the examples in the specification recited with a publication reference or patent number are the following (see specification at pages 29-34): genes conferring male sterility (U.S. Patent No. 3,861,709, U.S. Patent No. 3,710,511, U.S. Patent No. 4,654,465, U.S. Patent No 5,625,132, and U.S. Patent No. 4,727,219, incorporated by reference); male-sterility restorer genes (U.S. Patent Nos. 5,530,191, 5,689,041, 5,741,684, and 5,684,242, incorporated by reference); a herbicide resistant EPSPS mutation termed *aroA* (U.S. Patent 4,535,060); and a

mutant maize gene encoding a protein with amino acid changes at residues 102 and 106 (PCT Publication WO 97/04103).

The single locus traits are also described by way of PCT Application Publ. WO 95/06128, which was specifically incorporated by reference at page 31 of the specification. Examples of some of the single locus traits described in WO 95/06128, including any associated phenotype and publication reference given, are as follows:

the uidA gene from *E. Coli* encoding β-glucuronidase (GUS) (cells expressing *uidA* produce a blue color when given the appropriate substrate, Jefferson, R.A. 1987. *Plant Mol. Biol. Rep* 5: 387-405); the *bar* gene from *Streptomyces hygroscopicus* encoding phosphinothricin acetyltransferase (PAT) (cells expressing PAT are resistant to the herbicide Basta, White, J., Chang, S.-Y.P., Bibb, M.J., and Bibb, M.J. 1990. *Nucl. Ac. Research* 18: 1062); the *lux* gene from firefly encoding luciferase (cells expressing *lux* emit light under appropriate assay conditions, deWet, J.R., Wood, K.V., DeLuca, M., Helinski, D.R., Subramani, S. 1987. *Mol. Cell. Biol.* 7: 725-737); the *dhfr* gene from mouse encoding dihydrofolate reductase (DHFR) (cells expressing *dhfr* are resistant to methotrexate; Eichholtz, D.A., Rogers, S.G., Horsch, R.B., Klee, H.J., Hayford, M., Hoffman, N.L., Bradford, S.B., Fink, C., Flick, J., O'Connell, K.M., Frayley, R.T. 1987. *Somatic Cell Mol. Genet.* 13: 67-76); the *neo* gene from *E.Coli* encoding aminoglycoside phosphotransferase (APH) (cells expressing *neo* are resistant to the aminoglycoside antibiotics; Beck, E., Ludwig, G., Auerswald, E.A., Reiss, B., Schaller, H. 1982. *Gene* 19: 327-336); the *amp* gene from *E. Coli* encoding β-lactamase (cells expressing β-lactamase produce a chromogenic compound when given the appropriate substrate; Sutcliffe, J.G. 1978. *Proc. Nat. Acad. Sci.* USA 75: 3737-3741); the *xylE* gene from *Ps. putida* encoding catechol dihydroxygenase (cells expressing *xylE* produce a chromogenic compound when given the appropriate substrate; Zukowsky *et al.* 1983. *Proc. Nat. Acad. Sci.* USA 80: 1101-1105); the R,C1 and B genes from maize encode proteins that regulate anthocyanin biosynthesis in maize (Goff, S., Klein, T., Ruth, B., Fromm, M., Cone, K., Radicella, J., Chandler, V. 1990. *EMBO J.:* 2517-2522); the ALS gene from *Zea mays* encoding acetolactate synthase and mutated to confer resistance to sulfonylurea herbicides (cells expressing ALS are resistant to the herbicide; Gleen. Yang, L.Y., Gross, P.R., Chen, C.H., Lissis, M. 1992. *Plant Molecular Biology* 18: 1185-1187); the proteinase inhibitor II gene from potato and tomato (plants expressing the proteinase inhibitor II gene show increased resistance to insects; potato - Graham, J.S., Hall, G., Pearce, G., Ryan, C.A. 1986 *Mol. Cell. Biol.* 2: 1044-1051; tomato - Pearce, G., Strydom, D., Johnson, S., Ryan, C.A. 1991. *Science* 253: 895-898); the *Bt* gene from *Bacillus thuringensis* berliner 1715 encoding a protein that is toxic to insects (this gene is the coding sequence of *Bt* 884 modified in two regions for improved expression in plants; Vaeck, M., Reynaerts, A., Hofte, H., Jansens, S., DeBeuckeleer, M., Dean, C., Aeabeau, M., Van Montagu, M., and Leemans, J. 1987. *Nature* 328: 33-37); the *bxn* gene from *Klebsiella ozaeneae* encoding a nitrilase enzyme specific for the herbicide bromoxynil (cells expressing this gene are resistant to the herbicide bromoxynil; Stalker, D.m., McBride, K.E., and Malyj, L. *Science* 242: 419-422, 1988); the WGA-A gene encoding wheat germ agglutinin (expression of the WGA-A

gene confers resistance to insects; Smith, J.J., Raikhel, N.V. 1989. *Plant Mol. Biology* 13: 601-603); the *dapA* gene from *E. coli* encoding dihydrodipicolinate synthase (expression of this gene in plant cells produces increased levels of free lysine; Richaud, F., Richaud, C., Rafet, P. and Patte, J.C. 1986. *J. Bacteriol.* 166: 297-300); the *Z10* gene encoding a 10kd zein storage protein from maize (expression of this gene in cells alters the quantities of 10kD Zein in the cells; Kirihara, J.A., Hunsperger, J.P., Mahoney, W.C., and Messing, J. 1988. *Mol. Gen. Genet.* 211: 477-484); the Bt gene cloned from *Bacillus thuringensis* Kurstaki encoding a protein that is toxic to insects (the gene is the coding sequence of the cry IA(c) gene modified for improved expression in plants - plants expressing this gene are resistant to insects; Höfte, H. and Whiteley, H.R., 1989. *Microbiological Reviews.* 53: 242-255); the ALS gene from *Arabidopsis thaliana* encoding a sulfonylurea herbicide resistant acetolactate synthase enzyme (cells expressing this gene are resistant to the herbicide Gleen. Haughn, G.W., Smith, J., Mazur, B., and Somerville, C. 1988. *Mol. Gen. Genet.* 211: 266-271); the *dehl* gene from *Pseudomonas putida* encoding a dehalogenase enzyme (cells expressing this gene are resistant to the herbicide Dalapon; Buchanan-Wollaston, V., Snape, A., and Cannon, F. 1992. *Plant Cell Reports* 11: 627-631); the hygromycin phosphotransferase II gene from *E. coli* (expression of this gene in cells produces resistance to the antibiotic hygromycin. Waldron, C., Murphy, E.B., Roberts, J.L., Gustafson, G.D., Armour, S.L., and Malcolm, S.K. *Plant Molecular Biology* 5: 103-108, 1985); the *mtlD* gene cloned from *E. coli* (the gene encodes the enzyme mannitol-1-phosphate dehydrogenase; Lee and Saier, 1983. *J. of Bacteriol.* 153:685); the HVA-1 gene encoding a Late Embryogenesis Abundant (LEA) protein (the gene was isolated from barley; Dure, L., Crouch, M., Harada, J., Ho, T.-H. D. Mundy, J., Quatrano, R, Thomas, T, and Sung, R., *Plant Molecular Biology* 12: 475-486.

The foregoing represent just some of the single locus coding sequences that were known as of March 2, 1995; more than ***six years prior*** to the filing of the instant application. More than 25 regulatory elements were also described therein, as were numerous transformation vectors comprising combinations of these elements. Appellants could describe many more examples of single locus traits that were well known as of the filing date, and would be glad to do so should the Board find it useful. It thus goes without saying that single locus traits were more than well known to those of skill in the art as of the filing date and were fully described in the specification.

Techniques for the introduction of single locus traits by genetic transformation were further well known to those of skill in the art. Some of the transformation methods for corn that were well known as of the filing date and cited in the specification include the following: electroporation (U.S. Patent No. 5,384,253), microprojectile bombardment (U.S. Patent No.

5,550,318; U.S. Patent No. 5,736,369, U.S. Patent No. 5,538,880; and PCT Publication WO 95/06128), *Agrobacterium*-mediated transformation (U.S. Patent No. 5,591,616 and E.P. Publication EP672752), direct DNA uptake transformation of protoplasts (Omirulleh *et al.*, 1993) and silicon carbide fiber-mediated transformation (U.S. Patent No. 5,302,532 and U.S. Patent No. 5,464,765). Introduction of such traits by conventional breeding was also known. In fact, this is one of the most fundamental procedures in agricultural science, and it has not been alleged that this has not been described.

Appellants have therefore shown possession of the claimed male sterile plants and single locus conversions. Both large numbers of male sterility genes and single locus traits and the associated phenotypes were well known to those of skill in the art. The specification itself defines a single locus converted plant as comprising essentially all of the desired morphological and physiological characteristics of the starting non-converted plant, *e.g.*, I450436. Well more than an adequate number of examples have been provided and were known in the art to satisfy written description. The state of the art must be considered in the written description determination. As such, Appellants respectfully request reversal of the rejection.

2. Hybrid plants recited in claims 24 –26 have been fully described

a. The claimed hybrid plants share the genetic complement of corn variety I450436

Rejected claims 24-26 are directed to hybrid plants and seeds produced with corn plant I450436 as one parent. Appellants have fully described this claimed subject matter in compliance with the written description requirement of 35 U.S.C. §112, first paragraph. As set forth in the breeding history at pages 26-27 of the specification, corn plant I450436 is an inbred corn plant. All of the claimed hybrid plants having I450436 as a parent will therefore contain a copy of the same genome as corn plant I450436. That is, because I450436 is an inbred corn

plant, hybrid corn plants derived therefrom will have as half of their genetic material the same genetic contribution of corn plant I450436, save the possibility of the rare spontaneous mutation or undetected segregating locus. This entire genetic contribution of corn plant I450436 is described in the specification by way of the deposit of seed of corn plant I450436 with the ATCC. *See Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1330 (Fed. Cir. 2002) (holding that a biological deposit constitutes a written description of the deposited material under 35 U.S.C. §112, first paragraph). This represents a description of concrete and identifiable structural characteristics defining the claimed hybrid plants and distinguishing them from other plants in full compliance with the written description requirement.

The Federal Circuit has noted that such shared identifiable structural features are important to the written description requirement. *The Regents of The University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997) (noting that a name alone does not satisfy the written description requirement where "it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, *as one can do with a fully described genus, visualize or recognize the identity of the members of the genus*" (emphasis added)). Here, all of the members of the claimed genus of hybrids having I450436 as one parent share the structural feature of having the genetic complement of I450436. One of skill in the art could thus readily identify the members of the genus. The written description requirement has, therefore, been fully complied with.

b. The shared characteristics of the claimed hybrid plants are readily identified and described in the specification

As set forth above, the claimed F1 hybrid plants having I450436 as one parent will share the same genetic complement received from I450436. This is readily identifiable by genetic

marker analysis, as shown in Tables 6 and 8 of the specification. There shown is the SSR genetic marker profile of corn variety I450436, as well as an the exemplary hybrid plant designated 8018717 that was made using I450436 as one parent. As can be seen, hybrid corn plant 8018717 has the SSR genetic marker profile of I450436, and also includes the genetic markers from the second parent plant used to make the hybrid. The same will be true for any other hybrid plant having I450436 as one parent, save for an occasional difference at a locus due to spontaneous genetic rearrangements, which occur at statistically insignificant frequencies in essentially all organisms.

The second plant that is used to make the claimed hybrid plants is irrelevant, as a hybrid will be produced any time corn plant I450436 is crossed with a second plant. That is, any second plant capable of reproduction may be used to make the hybrid plant. Appellants cannot therefore be said to lack written description for the second genetic complement. This is particularly so given that hundreds or even thousands of different inbred corn lines were well known to those of skill in the art prior to the filing of the instant application, each of which could be crossed to make a hybrid plant within the scope of the claims. This is evidenced by a review of the U.S.P.T.O. patent data website, which reveals more than 300 utility patents issued on different corn varieties issued prior to the filing date of the current application. Any one of these corn plants, or the many hundreds or thousands of other maize plants that were known at the time the application was filed, could be used to produce an F1 hybrid plant having corn variety I450436 as one parent, and each of these would share the genetic complement of I450436.

Written description is reviewed from the perspective of one of skill in the art at the time the application is filed. *Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 863 (Fed. Cir. 1993). The specification need not disclose what is well-known to those skilled in the art and preferably

omits what is well-known and already available to the public. *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991). As ***any*** second plant may be used to produce the claimed hybrid plants and such plants were well known to those of skill in the art, Appellants cannot be said to have not been in possession of the second parent plant. The claimed hybrid corn plants have therefore been described in compliance with 35 U.S.C. §112, first paragraph.

The Examiner attempts to downplay the significance of the genetic marker data given in the specification by stating that some loci may be shared by other plants, that primer sequences are not described or that certain isozyme markers are not informative. However, no effort has been made to show that any substantial number of marker loci actually ***are*** shared by other plants. Further, Appellants do not claim such "other" plants, so this is irrelevant to written description. No basis has been provided to conclude that the claimed hybrid plants are not distinct and clearly identifiable by the genetic marker profile that has been set forth. Regarding the availability of genetic markers, the service that was used to detect SSR markers is commercially available to the public. Further, SSR and any of the other genetic marker systems that are well known to those of skill in the art may potentially be used, as is described on pages 60-61 of the specification. Regardless of whether SSR markers are used, the shared genetic complement of the claimed hybrid plants having corn variety I450436 as one parent distinguishes them. As the entire genome of corn variety I450436 has been described, at least, by way of the seed deposit that has been made, any polymorphic locus could be used including or in addition to the SSR markers shown in Tables 6 and 8.

c. The entire genetic complement of soybean variety 961905802272 is described by way of the proffered deposit of seed

The Examiner alleges that Appellants have not disclosed the genetic complement of this variety that is shared by each of the claimed hybrid plants and seeds. It is thus alleged that the

genetic contribution of variety I450436 could not be distinguished and is not described. This is incorrect, however, as Appellants describe the entire genetic sequence of soybean variety I450436 by way of a deposit of seed of the variety.

The Federal Circuit has recently held that a biological deposit may be used to satisfy written description for nucleic acids, whether the nucleic acid sequence is set forth in the specification or not. Specifically, in *Enzo Biochem, Inc. v. Gen-Probe Inc.*, the patent owner had deposited six strains of *N. gonorrhoeae* and claimed nucleotide sequences hybridizing to the nucleic acids of these strains, but the patent application did not set forth the nucleic acid sequences of these strains in the specification. 296 F.3d 1316, 1328 (Fed. Cir. 2002). The Federal Circuit nonetheless held that "as those bacteria were deposited, their ***bacterial genome is accessible*** and, under our holding today, they are ***adequately described in the specification by their accession numbers***." *Id.* (emphasis added). In its holding, the Federal Circuit considered the burden that would be placed on applicants were they required to sequence each of the strains, noting lower court findings that it would have taken 3,000 scientists a month to sequence the bacterial genome of one strain of *N. gonorrhoeae. Id.* In the instant case, even more effort would be required, as corn is a higher life form with a more complex genome than the bacteria deposited in *Enzo*. The Examiner would nonetheless appear to require this much of Appellants in direct contradiction of *Enzo*.

The fact that the deposit here will be made after the filing date of the application has no bearing on written description, as the Federal Circuit has noted that insertion of an accession number for a deposit after the filing date adds no new matter to a case provided the deposited subject matter is clearly identified in the application. See *In re Lundak*, 773 F.2d 1216, 1217 (Fed. Cir. 1985) ("....an accession number and deposit date add nothing to the written

description of the invention"). Appellants have therefore fully described the shared structure of the claimed hybrid plants at the nucleic acid level and thus have fully complied with 35 U.S.C. §112, first paragraph.

d. The Examiner's allegations that the expression of the genetic complement of corn variety I450436 is unpredictable are inapposite

The Examiner alleges that claimed hybrid plants have not been described despite inheriting the genetic complement of variety I450436 because information is not provided regarding the morphological and physiological traits of the hybrid plants. It is alleged that how the genes that are inherited would be expressed or would interact has not been shown. However, this misses the point that Appellants have gone one step further than morphological and physiological traits by describing the claimed hybrid plants at the genetic level. A better description could not be made than at the genetic level. Morphological and physiological traits, while helpful, are also subject to environmental variation and require subjective gradations. Genetic testing goes to the source of traits and yields concrete values.

The law further makes no distinctions regarding the manner in which applicants choose to describe claimed compositions. Rather, an applicant must merely describe the claimed subject matter by "whatever characteristics sufficiently distinguish it." *Amgen v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206 (Fed. Cir. 1991). Here, Appellants have described the genetic complement of parent plant I450436 that will be comprised in the claimed hybrid plants. This has been achieved using the SSR and isozyme genetic marker profiles given in tables 6-9 of the specification. Indeed, Appellants describe the entire genetic complement of parent plant I450436 by way of a seed deposit made with the ATCC, as set forth above, as described above. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1330 (Fed. Cir. 2002).

e. Appellants fully describe an exemplary hybrid made using inbred I450436

Further description of claimed hybrid plants is also provided in the specification by way of a detailed description of hybrid 8018717, which was produced with I450436 as one inbred parent. This plant is representative of hybrids produced using I450436 as one parent, each of which comprise the genetic complement of the parent corn plant as set forth above. Table 4 of the specification gives the performance characteristics for 8018717 and provides comparisons against other hybrid varieties. In Table 5, the morphological traits of 8018717 are given. The SSR and isozyme marker profiles for hybrid 8018717 are given in Tables 8 and 9, respectively. This information, combined with the descriptions of I450436 in the specification and the shared structure among hybrids having corn plant I450436 as a parent, is more than adequate to describe the claimed subject matter.

3. The rejection of claim 31 has been improperly issued and maintained

a. The rejection of claim 31 is improper

Claim 31 reads as follows:

31. A method of producing an inbred corn plant derived from the corn variety I450436, the method comprising the steps of:

(a) preparing a progeny plant derived from corn variety I450436 by crossing a plant of the corn variety I450436 with a second corn plant, wherein a sample of the seed of the corn variety I450436 was deposited under ATCC Accession No. PTA-4495;

(b) crossing the progeny plant with itself or a second plant to produce a seed of a progeny plant of a subsequent generation;

(c) growing a progeny plant of a subsequent generation from said seed and crossing the progeny plant of a subsequent generation with itself or a second plant; and

(d) repeating steps (b) and (c) for an addition 3-10 generations to produce an inbred corn plant derived from the corn variety I450436.

The position of the Examiner is that each product produced at any intermediate or penultimate step of the method is not adequately described. However, what is required to meet the written description requirement is that an Applicant show that he or she was in possession of the ***claimed***

invention. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). Here, a process is claimed, not a product of a process, and thus the steps of that process must be described, not intermediate or final products of the steps. The starting materials for the process must also be provided, otherwise the process could not be completed. However, the only starting materials required are corn variety I450436, which the Examiner does not allege to have not been described, and ***any*** second corn plant. As set forth above, corn plants were well known, and this has also therefore been fully described.

With respect to the steps, these have been fully set forth in the claim. It has not been alleged that any essential steps are absent. All that is required to complete the claimed method is to cross the corn variety I450436 or a product that is produced by any preceding step according to the steps given. All of the starting materials for any step within the method are either (1) corn variety I450436, (2) any second corn plant, or (3) a corn plant that is produced by following a preceding method step. The method has therefore been fully described.

It is also noted that corn breeding is well known to those of skill in the art. Without it, there would not be commercial corn varieties, which are typically sold as hybrids produced by crossing two inbred varieties. This is evidenced by the more than 300 issued patents to inbred maize varieties discussed above, given that inbred plants are not produced without multiple generations of intentional self-fertilization breeding steps. All of the steps recited in claim 31 are typical of the process used for the production of new corn varieties, save for the point of novelty, corn variety I450436. This is evidenced in the breeding history for the production of corn variety I450436, which is given in the specification. The specification also describes methods for producing new corn varieties in the review of related art, for example, at pages 2-4 of the application.

In conclusion, all steps of the claimed process have been recited, all starting materials have been fully described, and methods of producing new corn varieties were well known to those of skill in the art. Claim 31 has therefore been fully described in compliance with 35 U.S.C. §112, first paragraph. Reversal of the rejection is thus respectfully requested.

b. The Examiner has failed to adequately support the rejections

The Examiner has cited the Written Description Guidelines, Fed. Reg. Vol. 66, pp1099-1111 (Jan. 5, 2001), as allegedly supporting the rejection. A review of this section finds no support for the position taken. It is respectfully submitted that the Guidelines have been applied by the Examiner in the context of product-by-process claims, not process claims. Nowhere does the comment state that process and composition claims are analyzed in the same manner. Indeed, Appellants note that the initial analysis of written description set forth under the Guidelines involves "(i) Determine whether the application as filed describes the complete structure (***or*** acts of a ***process***) of the claimed invention as a whole." (emphasis added). Elsewhere in the guidelines the same distinction is made. The Guidelines therefore fail to support and contradict the position taken by the Examiner.

Findings of fact and conclusions of law by the U.S. Patent and Trademark Office must be made in accordance with the Administrative Procedure Act ("APA"). 5 U.S.C. § 706(A), (E), 1994; *see also In re Zurko,* 59 USPQ 2d 1693 (Fed. Cir. 2001). In particular, the Federal Circuit has held that findings by the Board of Patent Appeals and Interferences must be supported by "substantial evidence" within the record pursuant to the APA. *See In re Gartside,* 203 F.3d 1305, 1314-15 (Fed. Cir. 2000). Thus, an Examiner's position on Appeal must be supported by "substantial evidence" within the record in order to be upheld by the Board of Patent Appeals and Interferences. As demonstrated above, the current rejections are unsupported in fact or law.

The standards of the APA have therefore not been met and reversal of the rejection is thus respectfully requested.

C. **The Claims Are Enabled Under 35 U.S.C. §112, First Paragraph**

1. Male Sterile Plants and Conversions of Variety I450436 are Enabled

The Examiner rejects claims 16 and 24-31 under 35 U.S.C. §112, first paragraph as not being enabled. Claims 16 and 27-30 are directed to corn plants of the claimed variety which comprise a single locus conversion or a nuclear or cytoplasmic gene conferring male sterility. The Examiner alleges that no guidance has been provided for creation of such plants. However, this ignores the working example in the specification describing a single locus conversion that was made with a proprietary corn variety. This example gives the breeding history of the conversion that was made, including a description of seven backcrosses. The example describes exactly the type of process one of skill in the art could use to prepare conversions of the instant variety. The specification provides in great detail further guidance for creation of converted plants at pages 30-34. The techniques recited are also all well known in the art (*e.g.*, Poehlman *et al.*, 1995; Fehr, 1987; Sprague and Dudley, 1988).

With regard to creation of male sterile plants, this is also a technique that has been well-known for decades. This is evidenced by the numerous issued patents for creation of male sterile plants (see U.S. Patent No. 3,861,709; U.S. Patent No. 3,710,511; U.S. Patent No. 4,654,465; U.S. Patent No 5,625,132; U.S. Patent No. 4,727,219; U.S. Patent No. 5,530,191; U.S. Patent No. 5,689,041; U.S. Patent No. 5,741,684; and U.S. Patent No. 5,684,242, incorporated by reference).

The only basis alleged by the Examiner for the rejection is several references said to show the difficulty of making male sterile or single locus converted plants. However, these

references have not been shown to have any relevance to ***corn*** plants. Hunsperger deals with petunias; Kraft with sugar beets and Eshed with Tomatoes. The relevance of the references to the claimed invention has therefore not been established, as is specifically required to demonstrate a *prima facie* case of non-enablement.

Corn breeding is extremely advanced and well known in the art as evidenced by the descriptions in the specification and references cited therein. This is due in large part to the fact that corn is one of the world's major food crops and largest seed crops. As explained in the specification, North American farmers alone plant ***tens of millions of acres*** of corn at the present time and there are ***extensive national and international commercial corn breeding*** programs. It is respectfully submitted that this is not true of petunias, sugar beets and tomatoes.

The Examiner has also not provided any basis other than opinion to suggest why the genetics of any of petunias, sugar beets or tomatoes are relevant to corn. Each of these plants are widely genetically diverged from maize – they are each classified as dicotyledonous plants whereas maize is a monocotyledonous plants. This distinction was noted by the Federal Circuit in *Plant Genetic Systems v. DeKalb Genetics Corp.*, in which a finding on non-enablement was affirmed because the claims read on both monocotyledonous and dicotyledonous plants, but were only enabled for dicotyledonous plants. 315 F.3d 1335 (Fed. Cir. 2003).

It therefore appears that the Examiner has improperly placed the burden to show enablement on Appellants. The indication that the references concerning petunias, sugar beets and tomatoes apply to corn is made without any support. At the same time, the Examiner attempts to require Appellants to show why this is not true. While Appellants have nonetheless done so, it is respectfully notes that it is the ***Office*** that bears the burden of supporting its rejections. Findings of fact and conclusions of law by the U.S. Patent and Trademark Office

must be made in accordance with the Administrative Procedure Act ("APA"). 5 U.S.C. § 706(A), (E), 1994; *see also In re Zurko,* 59 USPQ 2d 1693 (Fed. Cir. 2001). In particular, the Federal Circuit has held that findings by the Board of Patent Appeals and Interferences must be supported by "substantial evidence" within the record pursuant to the APA. *See In re Gartside,* 203 F.3d 1305, 1314-15 (Fed. Cir. 2000). Thus, an Examiner's position on Appeal must be supported by "substantial evidence" within the record in order to be upheld by the Board of Patent Appeals and Interferences. The current rejections are unsupported as required by the APA and contrary to the evidence submitted by Appellants.

In view of Appellants example, detailed teaching in the specification and the failure to provide any basis to doubt the enablement of the claims, Appellants respectfully request that the rejection be reversed.

2. Production of Hybrid Plants is Enabled

Claims 24-26 are directed to hybrid corn seeds and plants grown therefrom which have the claimed variety as one parent. Appellants specification describes the creation of hybrid plant 8018717, which was produced with I450436 as one inbred parent. This working example provides a full enablement of the claims and no basis has been provided to conclude otherwise. The method used to make this plant, is exactly the same as would be used to make any other hybrid plant with I450436 as one inbred parent, because the method only requires crossing I450436 to ***any second plant***. This is because a hybrid plant is produced anytime the claimed variety is crossed with a second, different corn plant. Therefore, all that is required to enable the production on hybrid corn plants is that variety I450436 be fertile, which it is as evidenced by the working example described above. The Examiner therefore provides no basis to doubt this enablement.

With respect to availability of second parents, ***any second, different corn plant*** crossed to variety I450436 will produce the recited hybrid plants. There is therefore absolutely no basis for the enablement rejection. For the rejection to be supportable, one of skill in the art would have to be unable to obtain ***any*** second corn plant. However, thousands of corn varieties are known to those of skill in the art. More than 300 utility patents have been issued for corn varieties. A person can literally go to the local nursery or garden supply store and purchase such corn varieties. The Maize Genetics Cooperation Stock Center alone, which is supported by the U.S. Department of Agriculture and provides seed to the public, claims to have a collection approaching 80,000 individually pedigreed maize samples (see. http://w3.ag.uiuc.edu/maize-coop/mgc-info.html). There is, therefore, no basis to allege non-enablement of the full scope of the claims.

3. Claim 31 is Enabled

With regard to claim 31, all that is required to complete the method is for the claimed variety to be fertile and for one of skill in the art to follow the recited breeding steps. ***Any second corn plant*** may be employed in the method together with variety I450436. What other plant or plants one chooses to cross with the claimed variety is therefore ***completely irrelevant to enablement,*** as any fertile corn plant could be used to produce an inbred corn plant derived from the corn variety I450436. Further, the breeding steps recited are well known and fully described in the specification (see pages 2-5 and 50-53 of the specification). Enablement only requires that one of skill in the art be able to ***make and use the claimed invention*** without undue experimentation. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The specification has done this and thus fully meets the requirement.

In view of the foregoing reversal of the rejection is respectfully requested.

D. **The Rejection Under 35 U.S.C. §102 is Improper**

The Action has rejected claim 31 under 35 U.S.C. §102 as allegedly being anticipated. The position of the Examiner is that the claim is anticipated because multiple generations of breeding would cause the resultant product to "lose the genetic material from the starting material and be indistinguishable from the prior art plant."

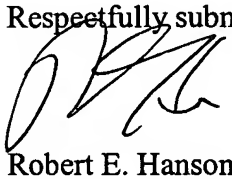
The rejection cannot survive even a cursory review. Claim 31 is a process claim that requires in step (a) "crossing a plant of the corn variety I450436 with a second corn plant." The Examiner has already acknowledged that corn variety I450436 is novel and nonobvious based on the lack of rejection of claim 1-15. All elements of claim 31 are therefore neither taught nor suggested by the prior art. The claim may therefore not be rejected under §102.

In view of the foregoing, reversal of the rejection is respectfully requested.

X. CONCLUSION

It is respectfully submitted, in light of the above, none of the pending claims lack written description. Therefore, Appellants request that the Board reverse the pending grounds for rejection.

Respectfully submitted,



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APPENDIX 1: CLAIMS ON APPEAL

16. The corn plant of claim 15, further comprising a nuclear or cytoplasmic gene conferring male sterility.

24. Hybrid corn seed produced by the process of claim 23.

25. A hybrid corn plant produced by growing a seed produced by the process of claim 23.

26. The hybrid corn plant of claim 25, wherein the plant is a first generation (F_1) hybrid corn plant.

27. The corn plant of claim 5, further defined as having a genome comprising a single locus conversion.

28. The corn plant of claim 27, wherein the single locus was stably inserted into a corn genome by transformation.

29. The corn plant of claim 27, wherein the locus is selected from the group consisting of a dominant allele and a recessive allele.

30. The corn plant of claim 27, wherein the locus confers a trait selected from the group consisting of herbicide tolerance; insect resistance; resistance to bacterial, fungal, nematode or viral disease; yield enhancement; waxy starch; improved nutritional quality; enhanced yield stability; male sterility and restoration of male fertility.

31. A method of producing an inbred corn plant derived from the corn variety I450436, the method comprising the steps of:

(a) preparing a progeny plant derived from corn variety I450436 by crossing a plant of the corn variety I450436 with a second corn plant, wherein a sample of the seed of the corn variety I450436 was deposited under ATCC Accession No. PTA-4495;

(b) crossing the progeny plant with itself or a second plant to produce a seed of a progeny plant of a subsequent generation;

(c) growing a progeny plant of a subsequent generation from said seed and crossing the progeny plant of a subsequent generation with itself or a second plant; and

(d) repeating steps (b) and (c) for an addition 3-10 generations to produce an inbred corn plant derived from the corn variety I450436.

APPENDIX 2: PENDING CLAIMS

1. A seed of the corn variety I450436, wherein a sample of the seed of the corn variety I450436 was deposited under ATCC Accession No. PTA-4495.

2. A population of seed of the corn variety I450436, wherein a sample of the seed of the corn variety I450436 was deposited under ATCC Accession No. PTA-4495.

3. The population of seed of claim 2, further defined as an essentially homogeneous population of seed.

4. The population of seed of claim 2, further defined as essentially free from hybrid seed.

5. A corn plant produced by growing a seed of the corn variety I450436, wherein a sample of the seed of the corn variety I450436 was deposited under ATCC Accession No. PTA-4495.

6. The corn plant of claim 5, having:
   (a) an SSR profile in accordance with the profile shown in Table 5; or
   (b) an isozyme typing profile in accordance with the profile shown in Table 6.

7. A plant part of the corn plant of claim 5.

8. The plant part of claim 7, further defined as pollen.

9. The plant part of claim 7, further defined as an ovule.

10. The plant part of claim 7, further defined as a cell.

11. The plant part of claim 10, wherein said cell is further defined as having :
   (a) an SSR profile in accordance with the profile shown in Table 5; or
   (b) an isozyme typing profile in accordance with the profile shown in Table 6.

12. A seed comprising the cell of claim 10.

13. A tissue culture comprising the cell of claim 10.

14. An essentially homogeneous population of corn plants produced by growing the seed of the corn variety I450436, wherein a sample of the seed of the corn variety I450436 was deposited under ATCC Accession No. PTA-4495.

15. A corn plant capable of expressing all the physiological and morphological characteristics of the corn variety I450436, wherein a sample of the seed of the corn variety I450436 was deposited under ATCC Accession No. PTA-4495.

16. The corn plant of claim 15, further comprising a nuclear or cytoplasmic gene conferring male sterility.

17. (A tissue culture of regenerable cells of a plant of corn variety I450436, wherein the tissue is capable of regenerating plants capable of expressing all the physiological and morphological characteristics of the corn variety I450436, wherein a sample of the seed of the corn variety I450436 was deposited under ATCC Accession No. PTA-4495.

18. The tissue culture of claim 17, wherein the regenerable cells comprise cells derived from embryos, immature embryos, meristematic cells, immature tassels, microspores, pollen, leaves, anthers, roots, root tips, silk, flowers, kernels, ears, cobs, husks, or stalks.

19. The tissue culture of claim 18, wherein the regenerable cells comprise protoplasts or callus cells.

20. A corn plant regenerated from the tissue culture of claim 17, wherein the corn plant is capable of expressing all of the physiological and morphological characteristics of the corn variety designated I450436, wherein a sample of the seed of the corn variety I450436 was deposited under ATCC Accession No. PTA-4495.

21. A process of producing corn seed, comprising crossing a first parent corn plant with a second parent corn plant, wherein one or both of the first or the second parent corn plant is a plant of the corn variety I450436, wherein a sample of the seed of the corn variety I450436 was deposited under ATCC Accession No. PTA-4495, wherein seed is allowed to form.

22. The process of claim 21, further defined as a process of producing F1 hybrid corn seed, comprising crossing a first inbred corn plant with a second, distinct inbred corn plant, wherein the first or second inbred corn plant is a plant of the corn variety I450436, wherein a sample of the seed of the corn variety I450436 was deposited under ATCC Accession No. PTA-4495.

23. The process of claim 22, wherein crossing comprises the steps of:

(a) planting the seeds of first and second inbred corn plants;

(b) cultivating the seeds of said first and second inbred corn plants into plants that bear flowers;

(c) preventing self pollination of at least one of the first or second inbred corn plant;

(d) allowing cross-pollination to occur between the first and second inbred corn plants; and

(e) harvesting seeds on at least one of the first or second inbred corn plants, said seeds resulting from said cross-pollination.

24. Hybrid corn seed produced by the process of claim 23.

25. A hybrid corn plant produced by growing a seed produced by the process of claim 23.

26. The hybrid corn plant of claim 25, wherein the plant is a first generation (F_1) hybrid corn plant.

27. The corn plant of claim 5, further defined as having a genome comprising a single locus conversion.

28. The corn plant of claim 27, wherein the single locus was stably inserted into a corn genome by transformation.

29. The corn plant of claim 27, wherein the locus is selected from the group consisting of a dominant allele and a recessive allele.

30. The corn plant of claim 27, wherein the locus confers a trait selected from the group consisting of herbicide tolerance; insect resistance; resistance to bacterial, fungal, nematode or viral disease; yield enhancement; waxy starch; improved nutritional quality; enhanced yield stability; male sterility and restoration of male fertility.

31. A method of producing an inbred corn plant derived from the corn variety I450436, the method comprising the steps of:

(a) preparing a progeny plant derived from corn variety I450436 by crossing a plant of the corn variety I450436 with a second corn plant, wherein a sample of the seed of the corn variety I450436 was deposited under ATCC Accession No. PTA-4495;

(b) crossing the progeny plant with itself or a second plant to produce a seed of a progeny plant of a subsequent generation;

(c) growing a progeny plant of a subsequent generation from said seed and crossing the progeny plant of a subsequent generation with itself or a second plant; and

(d) repeating steps (b) and (c) for an addition 3-10 generations to produce an inbred corn plant derived from the corn variety I450436.